

**Appendix A**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>In re Application of:</b>	)	
	)	
<b>Andre T. Baron et al.</b>	)	
	)	
<b>Serial No. 09/676,380</b>	)	<b>SOLUBLE EPIDERMAL</b>
	)	<b>GROWTH FACTOR RECEPTOR-</b>
<b>Filed: September 29, 2000</b>	)	<b>LIKE PROTEINS AND THEIR</b>
	)	<b>USES IN CANCER DETECTION</b>
<b>Art Unit: 1649</b>	)	<b>METHODS</b>
	)	
<b>Patent Examiner: Borgeest, Christina M.</b>	)	
	)	
<b>Our Ref: 07-277</b>	)	
	)	
<b>Confirmation No. 1919</b>	)	
_____	)	

**DECLARATION OF NITA J. MAIHLE, Ph.D.  
PURSUANT TO 37 C.F.R. § 1.132**

I, Nita J. Maihle, Ph.D., of New Haven, Connecticut, hereby declare that:

1. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application or any patent issued thereon.
2. I submit this Declaration in support of the Amendment and Request for Reconsideration filed on June 13, 2008 in U.S. Patent Application Serial No. 09/676,380 (hereinafter, "the '380 Application"), identified above and on which I am named as an inventor.

3. I earned my Ph.D. in Biomedical Sciences from Albert Einstein College of Medicine in 1983. I received additional Post-graduate training at Cold Spring Harbor Laboratory and National Cancer Institute (1983-1984) and Case Western Reserve School of Medicine (1984-1988).
4. I have held academic appointments at Mayo Clinic Comprehensive Cancer Center (Associate Director of Basic Sciences, 1994-1997; Program Director, Growth Factors and Cancer Program, 1995-1998), Mayo Clinic/Foundation Department of Biochemistry and Molecular Biology (Professor and Consultant, 1999-2003; Associate Professor and Consultant, 1992-1998; Assistant Professor and Senior Associate Consultant, 1989-1991), and Yale University School of Medicine Departments of Obstetrics, Gynecology, & Reproductive Sciences; Pathology; and Pharmacology (Professor and Member Yale Cancer Center, 2003-present).
5. I have advised numerous trainees over the course of my academic and professional careers and have taught numerous classes, both at the undergraduate and graduate levels.
6. Over the course of my career, my research projects have included studying cancer biology including etiology, detection, treatment, and prevention, and in particular ligand-independent signaling by ErbB receptor family members as well as soluble EGF/ErbB isoforms in tumor etiology and progression.
7. I have authored numerous peer-reviewed publications, review papers/editorials, and non-peer reviewed publications/conference proceedings, in the field of cancer biology including EGF/ErbB family expression and signal transduction in human tumors. A list of my publications is attached hereto as Exhibit 1.

8. I have been invited to make numerous oral presentations to a variety of audiences on topics related to the field of cancer biology. A list of my oral presentations is included in Exhibit 1 attached hereto.

9. I am a member of the following professional associations:

American Association for Cancer Research  
 Association for Women in Science  
 Connecticut Academy of Arts and Sciences (CAAS)  
 Molecular Epidemiology Working Group (AACR)  
 National Association for Women in Education  
 Women in Cancer Research (AACR)

10. I have held numerous professional appointments related to cancer research. A list of my professional appointments is included in Exhibit 1 attached hereto.

11. Over the course of my academic and professional careers, I have received numerous awards and honors for my research contributions, including:

2007	"Research and Leadership Innovation Award," Connecticut Technology Council
2007	"Y50K Award" (2 <sup>nd</sup> Place – Biotechnology Category), Yale School of Management/Yale Entrepreneurial Society
2007	"Y2K Award," (1 <sup>st</sup> Place – Biotechnology Category), Yale School of Management/Yale Entrepreneurial Society
2004	Pfizer, Visiting Professorship
2003	"Senior Women in Medicine Professorship," Yale University School of Medicine
2003	Eppley Visiting Professor of Oncology, Omaha, Nebraska
2001	"Faculty Recognition," Founding Director, Tumor Biology Program, Mayo Clinic
1999-2000	"Excellence in Teaching Recognition," Mayo Medical School
1998	"Teacher of the Year" Award, Mayo Graduate School
1994-1995	"Excellence in Teaching Recognition," Mayo Medical School
1993	"Business Advisor of Year" Award, INROADS
1988-89	USDA Postdoctoral Fellowship
1987-88	Florence B. Seibert Scholarship (AAUW Postdoctoral Fellowship)
1985-87	National Institute of Health NRSA Postdoctoral Fellowship
1984-85	Muscular Dystrophy Association Postdoctoral Fellowship
1983	Outstanding Young Women of America Award

1973-76      Ohio Board of Regents Scholarship

12. My education, training, experience, laboratory research, teaching experiences, and professional activities have enabled me to develop an expertise in various specialties within the cancer field, and particularly with regard to signal transduction by receptor tyrosine kinases, including members of the EGF/ErbB family.

13. Based on my educational background and work experience, I consider myself to be at least one skilled in the art of molecular and cellular biology, and particularly related to cancer and even more particularly in the area related to signal transduction by receptor tyrosine kinases, including members of the EGF/ErbB family.

14. I have read and am familiar with the '380 Application as it was filed in the U.S. Patent and Trademark Office and the claims of that application as currently pending in the Response to the Office Action filed herewith.

15. I have reviewed the Office Action issued for the '380 Application, which was mailed on April 14, 2008 (hereinafter, "Office Action"), including the new matter objection under 35 U.S.C. §132(a) related to the substitute sequence listing.

16. At the time of filing of Provisional Application Number 60/157,144 on September 30, 1999, from which the '380 Application claims priority, the inventors were in possession of the sequences disclosed in the '380 Application. As evidence thereof, please see attached hereto as Exhibit 2 the GenBank report documenting the submission of the "correct" sequences on February 1, 1999.

17. SEQ ID NO: 1 and SEQ ID NOs: 3-6 contain a one amino acid difference between the sequence as listed in the GenBank report and the sequence listing in the '380 Application located at position 540 (Lys should be Asn). See Exhibit 2. This is a conservative amino acid change that is not predicted to affect the function or structure of the proteins. It is also the site of a reported

HindIII polymorphism, which encodes either Asn or Lys, and therefore is not entirely incorrect, but rather reflects a naturally occurring sequence variant, which is documented in Guerin M. *et al.* Int. J. Cancer 43:201-208; Lee, J.S. *et al.*, Cancer Res. 48: 4045-4048; and Linnenbach A.J., Proc. Natl. Acad. Sci. USA 85: 74-78. The description of the sequences and proteins (both structure and function) in the specification, such as found in Examples I-III, is correct as filed.

18. In SEQ ID NO: 2, there are five independent discrepancies between the sequence listing of the application and the sequence submitted to GenBank and shown in the GenBank report attached hereto as Exhibit 2: 1) at position 706, 'a' should be 'c'; 2) at position 1865 'g' should be 'c'; 3) at position 2394 'a' should be 'g'; 4) positions 2435-2437 should be three 'c's instead of two; and 5) at position 2589 'g' should be 't'. SEQ ID NO: 2 corresponds with the protein sequence of SEQ ID NO: 1. Position 1865 corresponds with the HindIII polymorphism described above in ¶ 17 associated with the amino acid at position 540. The coding sequence of SEQ ID NO: 2 is 246-2363. Positions 2394, 2435, and 2589 are all in the 3'-UTR region outside of the coding region, thus they would not alter the structure of the translated protein product. In addition, we have unpublished preliminary data from the time of submitting these sequences that positions 2394 and 2589 are also likely sites of naturally occurring sequence polymorphisms (a/g at 2394 and g/t at 2589). These discrepancies, including position 706, are believed to be typographical errors in the sequence listing of the '380 Application, as further evidenced by the fact that the nucleotide sequence, SEQ ID NO: 2, has independent discrepancies from SEQ ID NO:1. No matter how these errors resulted, the nature of the errors is not significant in that they do not affect the structure or function of these proteins. Furthermore, the description of the

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Declaration of Nita J. Maihle, Ph.D.  
Filed in conjunction with Amendment  
and Request for Reconsideration filed on June 13, 2008*

sequence as found in the specification, such as Example I, is correct, including the description, isolation, primers, etc.

19. The overall nature, function, and description of the sequences in the '380 Application does not change by way of these amendments. The description of all of the sequences in the '380 Application are based on the "correct" sequences as found in the GenBank report attached hereto as Exhibit 2. These discrepancies are only in the sequence listing originally submitted with the '380 Application and not the specification.

20. The discrepancies between the GenBank sequences as shown in the GenBank report attached hereto as Exhibit 2 and the sequences listed in the '380 Application are minor in nature and one skilled in the art would readily associate the sequences as filed with those found in GenBank and further with "soluble" EGFR/ErbB1 as described in the '380 Application and subsequent publications. The amended sequence listing does not add new matter to the '380 Application. As a matter of accuracy, the sequence listing associated with the '380 Application should be amended.

21. Signed at New Haven, Connecticut, this 13<sup>th</sup> day of June, 2008.

Nita J. Maihle

## EXHIBIT 1

### BIBLIOGRAPHY

#### I. Publications

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## II. Recent Abstracts

1. Secord, A.A., Darcy, K.M., Armstrong, D., **Maihle, N.J.**, Miner, Z. (2007) Phase II study of cetuximab in combination with carboplatin in patients with relapsed platinum-sensitive ovarian or primary peritoneal carcinoma and evaluation of epidermal growth factor receptor immunohistochemical expression: A Gynecologic Oncology Group study. The Society of Gynecologic Oncologists Annual Meeting.
2. Baron, A.T., McAlpine, J.N., Wilken, J.A., Kim, M., Kimbler, K., Christensen, T.A., Zheng, W., Martel, M., Tavassoli, F.A., **Maihle, N.J.** (2006) Profiling EGFR isoforms in ovarian cancer demonstrates that EGFR and sEGFR have prognostic significance: Implications for EGFR isoforms as cancer biomarkers. AACR Molecular Diagnostics in Cancer Therapeutic Development, Chicago, IL.
3. Dealy, C.N., Fisher, M., Omi, M., Seghatoleslami, M.R., Clinton, G.M., Maihle, N.J., Iwamoto, R. Mekada, E., Mime, N. (2006) ErbB signaling in cartilage and bone development. 9<sup>th</sup> International Conference on Limb Development and Regeneration, Awaji, Japan.
4. Wilken, J.A., McAlpine, J.N., Zheng, W., Christensen, T.A., Shelton, B.J., Kimbler, K., Kim, M., Martel, M., Tavassoli, F.A., Reiter, J.L., Baron, A.T., **Maihle, N.J.** (2006) Prognostic significance of EGFR isoform expression in epithelial ovarian cancer. 6<sup>th</sup> Biennial Ovarian Cancer Research Symposium, Seattle, WA.
5. Wilken, J.A., McAlpine, J.N., Zheng, W., Christensen, T.A., Shelton, B.J., Kimbler, K., Kim, M., Martel, M., Tavassoli, F.A., Reiter, J.L., Baron, A.T., **Maihle, N.J.** (2006) Prognostic significance of EGFR isoform of expression in epithelial ovarian cancer. AACR Workshop in Cancer Research: Pathobiology of Cancer. Snowmass Village, CO.
6. Cleary, M.P., Grande, J.P., and **Maihle, N.J.** (2005) Prevention of mammary tumor development by intermittent caloric restriction. Importance of the manner in which calories are consumed. Era of Hope 2005 DoD Breast Cancer Research Program Meeting, Philadelphia, PA.
7. Reiter, J.L., Barrette, B.A., Christensen, T.A., Roman, G., Colon, J., and **Maihle, N.J.** (2005) Expression and characterization of novel EGFR isoforms in human placental tissues. 2<sup>nd</sup> Colloquium in Protein Structure, Function and Dynamics, San Juan, Puerto Rico.
8. Valle, B., **Maihle, N.J.**, and Cora, E.M. (2005) Shedding of EGFR is mediated by the ERK MAP kinase pathway. 96<sup>th</sup> Annual Meeting, American Association for Cancer Research, Anaheim, CA.
9. Negron-Vega, L., **Maihle, N.J.**, and Cora, E.M. (2005) The expression of a soluble isoform of EGFR (p110-sEGFR) is stimulated by EGF and PMA in the breast



- adenocarcinoma cell line MDA-MB-468. 96<sup>th</sup> Annual Meeting, American Association for Cancer Research, Anaheim, CA.
10. Nieves-Alicea, R., Rodriguez-Quinones, J.F., **Maihle, N.J.**, Reiter, J.L., and Cora, E.M. (2005) p110 sEGFR, a 110-kD isoform of epidermal growth factor receptor, interacts with ErbB-2 in the presence of EGF. 96<sup>th</sup> Annual Meeting, American Association for Cancer Research, Anaheim, CA.
11. McAlpine, J.N., Nossor, V., Martel, M., Christensen, T.A., Reiter, J.L., Tavassoli, F.A., Schwartz, P.E., and **Maihle, N.J.** (2005) Analysis of the prognostic utility of p110 soluble isoform and p170 full-length human EGF receptor expression in granulosa cell tumors of the ovary. 36<sup>th</sup> Annual Meeting, Society of Gynecologic Oncologists, Miami, FL.
12. Baron, A.T., Boardman, C.H., Lafky, J.M., Rademaker, A., Liu, D., Fishman, D.A., Podratz, K.C., and **Maihle, N.J.** (2004) Soluble epidermal growth factor receptor (sEGFR) and (CA125): Screening and/or diagnostic tests of ovarian cancer? 5<sup>th</sup> Biennial Ovarian Cancer Research Symposium, Marsh Rivkin Center for Ovarian Cancer Research, Seattle, WA.
13. Cleary, M.P., Grande, J.P., and **Maihle, N.J.** (2004) Effect of body weight on development of estrogen receptor-negative mammary tumors in transgenic MMTV-neu mice. Third Annual American Association for Cancer Research International Conference Frontiers in Cancer Prevention Research, Seattle, WA.
14. Cleary, M.P., Grande, J.P., and **Maihle, N.J.** (2004) Dietary obesity does not impact development of estrogen receptor-negative mammary tumors in transgenic MMTV-neu mice. North American Association for the Study of Obesity's 2004 Annual Scientific Meeting, Las Vegas, NV.
15. Baron, A.T., Boardman, C.H., Lafky, J.M., Rademaker, A., Liu, D., Fishman, D.A., Podratz, K.C., and **Maihle, N.J.** (2004) Soluble epidermal growth factor receptor (sEGFR/sErbB1) and cancer antigen 125 (CA125) as screening and diagnostic tests of epithelial ovarian cancer. 95<sup>th</sup> Annual Meeting, American Association for Cancer Research, Orlando, Florida.
16. McAlpine, J.N., Zheng, W., Chambers, S.K., Christensen, T.A., Martel, M., Reiter, J.L., and **Maihle, N.J.** (2004) The p110 isoform of human EGF receptor is differentially expressed in serous vs. mucinous ovarian cancer. 95<sup>th</sup> Annual Meeting, American Association for Cancer Research, Orlando, Florida
17. McAlpine, J.N., Zheng, W., Chambers, S.K., Christensen, T.A., Martel, M., Tavassoli, F., Reiter, J.L., and **Maihle, N.J.** (2004) The expression of p110 soluble isoform and full-

- length p170 human EGF receptor in ovarian tumors: tissue microarray analysis of 404 cases. New England Gynecologic Oncology Association, Cape Cod, MA.
18. Negron, L., **Maihle, N. J.** and Cora, E. M. (2004) The expression of a 110-kD isoform of EGFR in MCF7 cells is regulated by EGF and PMA. Sixth Joint Conference of the American Association for Cancer Research and the Japanese Cancer Association, Waikoloa, Hawaii.
  19. Cleary, M. P., Grande, J. P., and **Maihle, N. J.** (2003) Leptin is a growth factor for breast cancer: Evidence from *in vitro* and *in vivo* studies. Adipose Tissue Secretory Function and its Role in Obesity-associated Co-morbidities (National Institutes of Health), Washington, D. C.
  20. Perez, M., **Maihle, N. J.**, and Cora, E. M. (2003) Epidermal growth factor receptor is shed from the breast adenocarcinoma cell line MDA-MB-468 through a regulated process. Advances in Breast Cancer Research Conference (American Association for Cancer Research), Huntington Beach, CA.
  21. Cleary, M. P., Hu, X., McCleary-Wheeler, A. L., Greenwood, T. M., Grande, J. P., and **Maihle, N.J.** (2003) Dietary obesity and elevated serum leptin levels are accompanied by shortened mammary tumor latency and increased mammary tissue leptin-receptor protein in MMTV-TGF $\alpha$  mice. Advances in Breast Cancer Research Conference (American Association for Cancer Research), Huntington Beach, CA.
  22. Roman, G., Colon, J., Christensen, T. and **Maihle, N.J.** (2003) Localization of a novel 1.8 kb EGF transcript in human placenta. COBRE Conference, University of Puerto Rico, San Juan, PR.
  23. Roman, G., Colon, J., Christensen, T., and **Maihle, N.J.** (2003) Localization of a novel 1.8 kb EGFR transcript in human placenta. Annual Biomedical Research Conference for Minority Students, San Diego, CA.
  24. Cleary, M. P., Hu, X., McCleary-Wheeler, A. L., Greenwood, T. M., Grande, J. P., and **Maihle, N.J.** (2003) Dietary obesity and elevated serum leptin levels are accompanied by shortened mammary tumor latency and increased mammary tissue leptin receptor protein in MMTV-TGF- $\alpha$ -mice. 2nd Annual International Conference on Frontiers in Cancer Prevention Research Conference (American Association for Cancer Research), Phoenix, Arizona.
  25. Omi, M., **Maihle, N. J.**, and Dealy, C. N. (2003) Role of EGF signaling in chick limb development. Japanese Society of Developmental Biologists, Japan.
  26. Omi, M., **Maihle, N. J.**, and Dealy, C. N. (2003) Role of EGF signaling in chick limb development. 62nd Annual Meeting Society of Developmental Biologists, Boston, MA

27. Reiter, J. L., Christensen, T. A., and **Maihle, N. J.** (2003) Alternative splicing and post-translational modifications contribute to diverse isoforms of the epidermal growth factor receptor. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada
28. Jones, M. B., Houwink, A. P., Lingle, W., Berchuck, A., Maxwell, G. L., Podratz, K. C., and **Maihle, N. J.** (2003) Steroid regulation of growth factors in endometrial carcinoma. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada.
29. Hu, X., McCleary-Wheeler, A. L., Greenwood, T. M., Grande, J. P., **Maihle, N. J.**, and Cleary, M. P. (2003) Differences in serum leptin, mammary tissue leptin receptor expression, mammary tumor latency, and tumor burden in obesity-prone and obesity-resistant mice fed a high diet. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada.
30. Boerner, J. L., Danielsen, A. J., Lovejoy, C. A., Wang, Z., Juneja, S. C., Faupel-Badger, J. M., Darce, J. R., Li, B., Shu, H.-K. G., and **Maihle, N. J.** (2003) Grb2 regulation of the actin-based cytoskeleton is required for ligand-independent EGF receptor-mediated oncogenesis. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada.
31. Nieves, R., **Maihle, N.J.**, and Cora, E. M. (2003) Dimerization of a soluble isoform of epidermal growth factor receptor (110 kD-sEGFR) in the presence of bis (sulfosuccinimidyl) suberate. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada.
32. Perez, M., **Maihle, N. J.**, and Cora, E. M. (2003) Purification and Characterization of a soluble isoform of the epidermal growth factor receptor from the breast carcinoma cell line MDA-MB-468. 94th Annual Meeting of the American Association for Cancer Research, Toronto, Canada.
33. Valle, B., Carmona, C., **Maihle, N.J.**, and Valent, G., and Cora, E. M. PMA increases expression of a soluble isoform of epidermal growth factor receptor (110 kD-sEGFR) in MCF-7 cells. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada
34. Lee, H., Owen, B. A., and **Maihle, N. J.** (2003) p85-sErbB3 binds to heregulin as a monomer and can complex with cell surface ErbB3 and ErbB4 receptors in an heregulin-dependent manner. 94th Annual Meeting American Association for Cancer Research, Toronto, Canada.
35. Cleary, M. P., Hu, X., Juneja, S. C., Grand, J. P., and **Maihle, N. J.** (2003) Leptin receptor-deficient mice do not develop oncogene-induced mammary tumors (MTs). 94th Annual Meeting of the American Association for Cancer Research, Toronto, Canada.

36. Fishman, D. A., **Maihle, N. J.**, Baron, A. T., Petricoin, E., Liotta, L., Graves, L., So, J., and Stack M. S. (2003) The National Ovarian Cancer Early Detection Program. Society of Gynecologic Investigation Annual Meeting, Washington, D. C.

### **III. Invited Presentations**

1. **(Extramural)**
1. Trinity College, HHMI-sponsored Undergraduate Research Program, Hartford, CT, April, 2008
2. Innovation and Reform in Clinical Trial Design: Implementation of Biomarkers in Clinical Trial Design, Toronto, Canada, October, 2007
3. Connecticut Technology Council, 2008 Women of Innovation Plenary Speaker, New Haven, CT, August, 2007
4. University of Maryland Medical Center, Molecular Pathology Program, Baltimore, MD, June, 2007
5. Gynecologic Oncology Group, 2007 Semi-Annual Meeting, San Diego, CA, January, 2007
6. Roswell Park Cancer Institute, September, 2006
7. Albert Einstein College of Medicine, Dept. of Anatomy and Structural Biology, Bronx, NY, June, 2006
8. Mount Sinai School of Medicine, Dept. of Oncological Sciences Lecture Series, New York, May, 2005
9. Annual Lynn Cohen Foundation for Ovarian Research Symposium, New York, NY, April 2005
10. Receptor BioLogix, San Francisco, CA, November, 2004
11. Pfizer Global Research and Development, Groton, CT October, 2004
12. University of New Mexico Cancer Center, Albuquerque, New Mexico, March, 2004
13. Ventana Medical Systems, Tucson, AZ, March, 2004
14. North Dakota State University, Women's Studies Symposium, Fargo, ND, March, 2004

15. Eppley Visiting Professor of Oncology, (Course moderator and lecturer, "Biology of Breast Cancer"), Omaha, NE, May, 2003
16. AACR Meet-the-Expert Sunrise Session, "Soluble EGFR/ErbB Receptors: Form, Function, and Clinical Utility as Serum Biomarkers," Washington, DC, July, 2003
17. Yale School of Medicine, Pathology Grand Rounds, New Haven, CT, February, 2003
18. Pfizer Global Research and Development (Oncology Division), Groton, CT, February 2003
19. "Colloquium on Protein Structure, Function, and Dynamics: Frontiers in Protein Spectroscopy," Ponce, Puerto Rico, February, 2003
20. Van Andel Cancer Research Institute, Grand Rapids, MI, January, 2003
21. ASCO Molecular Therapeutics Symposium, "Receptor Tyrosine Kinase Inhibitors in the Treatment of Gynecologic Malignancies," San Diego, California, November, 2002 (Co-moderator and Speaker)
22. Robert H. Lurie Comprehensive Cancer Center of Northwestern University and Northwestern Memorial Hospital's Ovarian Cancer Early Detection Conference, Chicago, IL, September, 2002
23. Fox Chase Cancer Center, Ovarian Cancer Research Program, Philadelphia, PA, August, 2002
24. Yale School of Medicine, Department of Obstetrics/Gynecology, New Haven, CT, June, 2002
25. Huntsman Cancer Center, University of Utah Medical School, Salt Lake City, Utah, May, 2002
26. Molecular Mechanisms Underlying Ovarian Cancer: Implications for Prevention and Treatment, University of Pittsburgh Cancer Institute, Pittsburgh, PA, May, 2002 (Session Chair)
27. Gordon Research Conference, "New Frontiers in Cancer Detection and Diagnosis," Ventura Beach, CA, March, 2002
28. Society for Gynecologic Investigation, Los Angeles, CA, March, 2002
29. Oklahoma University Health Sciences Center, Department of Biochemistry and Molecular Biology, February, 2002

30. University of Illinois at Chicago Medical School, Chicago, IL, Department of Pharmaceutics and Pharmacodynamics, January, 2002
31. University of Puerto Rico Medical School, San Juan, PR, Department of Biochemistry, December, 2001
32. University of Puerto Rico, Mayaguez, PR, Department of Chemistry, December, 2001
33. University of Maryland Medical School, Baltimore, MD, Molecular and Cell Biology Program, December, 2001
34. Brown University Medical School, Providence, RI, July, 2001
35. University of California San Francisco Cancer Center, May, 2001
36. Bi-annual Tumor Markers Conference, Santa Barbara, CA, March, 2001
37. University of Texas Medical Center, Department of Molecular Medicine, San Antonio, TX, February, 2001
38. Cleveland Clinic Cancer Center, December, 2000
39. University of Wisconsin Medical School, November, 2000
40. University of Minnesota, Department of Pharmacology, November, 2000
41. University of North Dakota, School of Medicine, Department of Biochemistry, October, 2000
42. Northwestern University Medical School, Department of Pharmacology, September, 2000
43. First Annual Early Detection Research Network Scientific Workshop, Chicago, Illinois, September, 2000
44. Ovarian Cancer 2000: Translational Research: Outcomes and Opportunities, Seattle, Washington, September, 2000
45. NCI Workshop on Ovarian Cancer Screening, Bethesda, Maryland, September, 2000
46. Washington University, Department of Obstetrics and Gynecology, St. Louis, Missouri, August, 2000
47. University of Pittsburgh Cancer Center, July, 2000

48. Fred Hutchinson Cancer Center (Ovarian SPORE Program), Seattle, Washington, July, 2000
49. Oregon Health Sciences Cancer Center, Portland, Oregon, April, 2000
50. Ovarian Cancer Prevention Workshop, Sponsored by NCI Division of Cancer Prevention, San Francisco, CA, March, 2000
51. Co-chair, AACR Minisymposium, "HER2 in Breast Cancer and Other Malignancies," April, 2000
52. Co-chair, AACR Minisymposium, "EGF Receptor Family Tyrosine Kinases," April, 2000
53. Society for Gynecologic Investigation Ovarian Cancer Symposium, Chicago, Illinois, March, 2000
54. Cleveland Clinic, Department of Cancer Biology, October, 1999
55. University of South Alabama, Department of Structural and Cell Biology, September, 1999
56. University of Wisconsin, Molecular Basis of Disease Program, December, 1998
57. University of Georgia, Department of Biochemistry, March, 1998
58. Minnesota Academy of Sciences Annual Symposium on Biomolecular Structure (Keynote Speaker), University of Minnesota, April, 1997
59. University of Puerto Rico Medical School (San Juan), Department of Biochemistry, February 1997
60. American Cancer Society, Minnesota Division, "Cancer and the New Biology," (Keynote Speaker) October, 1996
61. The Hormel Research Institute, University of Minnesota, May, 1996
62. Gustavus Adolphus College, Biochemistry Program, April, 1996
63. Jacksonville University and Mayo Clinic Jacksonville, Fourth Annual Women in Science Symposium, "Discovering Science: Women and Science in the '90's," (Keynote Speaker) April, 1996
64. St. Olaf College, Department of Chemistry, September, 1995

65. University of Puerto Rico, Department of Biochemistry, April, 1995
66. College of St. Catherine, Department of Biology, November, 1994
67. Iowa State University, Department of Biochemistry and Biophysics, November, 1993
68. Gustavus Adolphus College, Department of Chemistry, October, 1993
69. Winona State University ("Cancer and the New Biology"), April, 1993
70. University of Utah, Department of Pathology, February, 1992
71. Miami University, Biological Sciences, January, 1992
72. Children's Hospital and University of Cincinnati Medical School, Institute for Developmental Research, January, 1992
73. University of Wisconsin (Madison), Department of Physiological Chemistry, April, 1991
74. Albert Einstein College of Medicine, Department of Structural Biology, March, 1991
75. Emory University, Department of Biochemistry, November, 1990
76. University of Florida (Gainesville), Department of Tumor Biology, February, 1990
77. University of Wisconsin (Madison), Department of Tumor Virology, August, 1988
78. University of Georgia, School of Veterinary Medicine, July, 1988
79. Oklahoma Medical Research Foundation, Department of Cell and Molecular Biology, June, 1988
80. M.D. Anderson, Department of Molecular Genetics, May, 1988
81. M.D. Anderson, Department of Tumor Biology, May, 1988
82. Harvard Medical School, Department of Medicine, May, 1988
83. Case Western Reserve School of Medicine, Department of Pharmacology, February, 1988
84. Cleveland State University, Department of Biology, March, 1987

***(Intramural)***  
***Yale University***



1. Women's Leadership Conference at Yale, November, 2007
2. Frankly Speaking About Lung Cancer, Yale Cancer Center, November, 2007
3. "Y50K Finalist" (Biotechnology Category), Yale School of Management/Yale Entrepreneurial Society, April, 2007
4. Vascular Biology and Transplant Program, February, 2007
5. School of Medicine "Grantsmanship 101: The NIH Grant Application and Review Process," November, 2006
6. Thoracic Oncology Annual Research Conference, November, 2006
7. Ob/Gyn Departmental Research in Progress Seminar, "Biomarker Assays and Cancer: Applications in the Study of Breast and Ovarian Cancer," February, 2006
8. Office for Women in Medicine at Yale, Career Opportunities Seminar," The Pfizer Visiting Professor Program: What It Is, How to Apply," January, 2006
9. Connecticut State Chest Seminar, "Targeted Cancer Chemotherapy: The ErbB/EGF Receptor Family as a Paradigm," January, 2006
10. Morse College Fellows Lecture Series, "What Lies beneath the Surface: The Early Detection of Cancer," September, 2005
11. Mellon Forum (Morse College), "The Early Detection of Breast and Ovarian Cancer – A Research Seminar as a Public Speaking Paradigm," September, 2005
12. Pharmacology Departmental Seminar Series, February 2004
13. Pathology Grand Rounds, Bridgeport Hospital, Bridgeport, CT, December, 2003
14. Ovarian Cancer Research Program, Yale Cancer Center, October 2003

***Mayo Clinic***

1. Neuro-oncology Research Program, "Soluble ErbB/EGF Receptor Isoforms," June, 2003
2. Endocrine Research Seminar Series, "Isolation and Characterization of EGF Receptor Isoforms:
3. Expression in Human Placenta," February, 2002

4. Mayo Clinic, Scottsdale, Department of Biochemistry, "sErbB1: A Novel Prognostic and Diagnostic Serum Biomarker in Ovarian Cancer," October, 1999
5. Mayo Clinic, Women's Health Grand Rounds, "New Markers for the Detection of Ovarian Cancer," July, 1999
6. Department of Medicine, Division of Gastroenterology, "GI Research Seminar Series," January, 1999
7. Department of Oncology, Core Curriculum Lecture Series, "Oncogenes and Tumor Suppressors," September, 1998
8. Department of Laboratory Medicine, Molecular Genetics Continuing Education Lecture, September, 1998
9. Mayo Graduate School, "Research at Mayo - Summer Student Seminar Series," July, 1998
10. Mayo Graduate School, NIH Grant Writing Workshop, December, 1996
11. Department of Oncology, Core Curriculum Lecture Series, "Introduction to Cancer Biology," August, 1996
12. Department of Oncology, Core Curriculum Lecture Series, "Oncogenes," August, 1996
13. Mayo Graduate School, "Cancer and the New Biology," June, 1996
14. Mayo Clinic, Health Concerns of Women Patients, "Genetics for the Generalist," October, 1995
15. Mayo Graduate School, "Life After Graduate School," (panel discussion) February, 1995
16. Mayo Graduate School, "Research at Mayo - Summer Student Seminar Series," June, 1994
17. Mayo Oncology Society, "Mechanisms of Escape from Hormonal Regulation in Breast and Prostate Cancer," April, 1994
18. Department of Oncology, Core Curriculum Lecture Series, "Cancer Biology: Oncogenes," March, 1994
19. Department of Medical Oncology, Core Curriculum Lecture Series, "Cancer Biology: Tumor Suppressors," March, 1994
20. Molecular Neurosciences, Mayo Graduate School, December, 1993

21. Mayo Graduate School, "Research at Mayo - Summer Student Seminar Series," June, 1993
22. Mayo Clinic, Medical Grand Rounds, "A Program in Women's Cancers: Strengths of the
23. Clinical-Laboratory Interface," May, 1993
24. Continuing Medical Education Conference (Oncology), April, 1993
25. Mayo Research Society, November, 1992
26. Mayo Graduate School, "Research at Mayo - Summer Student Seminar Series," August, 1992
27. Department of Neurology, August, 1992
28. Mayo Medical Laboratories, "Controversies in Serum Tumor Markers," May, 1992
29. Mayo Clinical Chemistry Conference, April, 1992
30. Department of Medical Oncology, Core Curriculum Lecture, February, 1992
31. Orthopedic Research, July, 1991
32. Sigma Xi Science Teachers' Workshop, June, 1991
33. Cell Biology Interest Group, January, 1990
34. Oncology Research, December, 1989
35. Department of Immunology, November, 1989
36. Department of Biochemistry and Molecular Biology, April, 1988

***(Workshop participant)***

1. Pfizer Global Research and Development – WISAY: Women's Leadership Network Panel Member, Groton, CT, 2008
2. Pittsburgh Life Sciences Greenhouse, "SBIR Grant Writing Boot Camp", August, 2007
3. Yale School of Management, "Business Of Biotechnology Minicourse Series", February, 2007

4. Yale University Office of Research Administration, "Sponsored Projects Administration for Faculty", January, 2007
5. Yale Graduate School, "Graduate Student Development: A 3 Stage Model to Inform Services & Programs", December, 2006
6. Yale University Human Investigatory Committee, "New Regulatory and Ethical Developments in Human Subjects Protection", December, 2006.
7. Yale University Organizational and Development Learning Center, "Managing Time through the 4 D's", February 2006, New Haven, CT
8. 7th Annual NIH SBIR/STTR Conference, July 2005, Bethesda, MD
9. Lecturer, Cancer Education Consortium, "Cancer and Growth Factor Receptors" and "Testing Cancer for HER2 Overexpression: Lessons Learned", Virginia Beach, VA, June, 2004
10. Third Early Detection Research Network Scientific Workshop, Bethesda, Maryland, June, 2004
11. Faculty Discussion Convener, "In the Company of Scholars: Yale Women in Changing World", Yale University, April, 2004
12. AACR Associate Member Grant Writing Workshop (Panel Member), July, 2003, Washington, DC
13. Mayo Foundation, "The Learning Organization," Staff Leadership Program, March, 2003, Rochester, MN
14. Mayo Foundation, "Conflict Management Strategies," Staff Leadership Program, December, 2002, Rochester, MN
15. Mayo Foundation, "Navigating Through Change," Staff Leadership Program, November, 2002, Rochester, MN
16. 4th Ovarian Cancer Research Symposium, "Integration of Research and Treatment," (Roundtable Discussion Panel Member), September, 2002, Seattle, WA
17. NCI Workshop on "Endometrial Cancer Biology" April, 2002, San Francisco, CA
18. Mayo Foundation, "Teaching Strategies and Principles of Adult Education," Staff Leadership Program, May, 2001, Rochester, MN

19. Gordon Research Conference "Reproductive Biology Tract," New London, Connecticut, July, 2000
20. Harvard Medical School, Harvard Macy Fellowship Program for Physician Educators (sponsored by Josiah Macy, Jr. Foundation Award), January and May, 2000, Boston, MA
21. NCI Workshop on "Ovarian Cancer," April, 2000, San Francisco, CA
22. Gynecologic Oncology Group, "Protocol Writing and Development Workshop," January, 2000, Tampa, FL
23. Mayo Foundation, "Preserving Mission and Values: Tools for Success in Today's Healthcare Environment," Staff Leadership Program, October, 1999, Rochester, MN
24. Mayo Foundation, "Understanding Professional Unease" [Prof. Miles Little], Staff Leadership Program, October, 1999, Rochester, MN
25. University of Pittsburgh, "Teaching Survival Skills and Ethics," June, 1999, Copper Mountain Resort, CO
26. Mayo Foundation, "Creatively Working With Others," Staff Leadership Program, March, 1999, Rochester, MN
27. Mayo Foundation, "Enhancing Individual Creativity," Staff Leadership Program, March, 1999, Rochester, MN
28. M. D. Anderson, "Tumor Markers at the Millennium," February, 1999, Santa Barbara, CA
29. Mayo Foundation, "Creating a Respectful Work Environment," Staff Leadership Program, December, 1998, Rochester, MN
30. Mayo Foundation, "Negotiating Healthcare: New Skills and Changing Models," Staff Leadership Program, November, 1998, Rochester, MN
31. National Association for Women in Education, "Institute for Emerging Women Leaders in Higher Education," November, 1998, College Park, MD
32. Mayo Foundation, "Building a Committed Workforce: Developing Ourselves, Our People and Our Team," Staff Leadership Program, November, 1998, Rochester, MN
33. University of Arizona, "Management of Biomedical Research Laboratories," October, 1998, Tucson, AZ (co-sponsored by the Office of Research Integrity)

34. Mayo Foundation, "Leadership Succession Planning," Staff Leadership Program, April, 1998, Rochester, MN
35. Mayo Foundation, "Coaching, Counseling, and Corrective Action," Staff Leadership Program, March, 1998, Rochester, MN
36. Mayo Foundation, "Negotiation and Conflict Resolution in the Academic Health Care Setting," Staff Leadership Program, March, 1998, Rochester, MN
37. Mayo Foundation, "Medical Law" (sessions I-III), January, 1998, Staff Leadership Program, Rochester, MN
38. Mayo Foundation, "Covey Program: Seven Habits of Highly Effective People," October, 1997, Rochester, MN
39. Mayo Foundation, "Introduction to the FDA Good Laboratory Practice Regulations," Staff Leadership Program, August, 1997, Rochester, MN
40. Mayo Foundation, "Enhancing Innovation," Staff Leadership Program, March, 1997, Rochester, MN
41. Mayo Foundation, "Just Doctors," Staff Leadership Program (on Diversity), November, 1996, Rochester, MN
42. Mayo Continuing Education Course, "Psychological Dimensions of Professional Life," Staff Leadership Program, October, 1996, Mayo Clinic, Rochester, MN AACR Sponsored Workshop on "Histopathobiology of Neoplasia," July, 1996, Keystone, CO
43. Mayo Foundation, "Taking Charge in Changing Times," Staff Leadership Program, May, 1996, Rochester, MN
44. Mayo Foundation, "Teamwork/Team Building," Staff Leadership Program, April, 1996, Rochester, MN
45. Mayo Foundation, "Chairing Meetings," Staff Leadership Program, April, 1996, Rochester, MN
46. Mayo Foundation, "Future Plans and Strategies," Staff Leadership Program, April, 1996, Rochester, MN
47. Mayo Foundation, "Managing Change," Staff Leadership Program, March 1996, Rochester, MN MNCURA, "Conflict of Interest and Misconduct in Science: Integrated Approaches to Regulatory Compliance," August, 1995, Keystone, CO

48. Mayo Foundation, "All Staff Leadership Development Program," January, 1995, Rochester, MN
49. Association of American Medical Colleges, "Ph.D. Education in American Medical Colleges," October, 1994, Fort Lauderdale, FL (inception of AAMC's GREAT Program)
50. NIH Consensus Development Conference "Ovarian Cancer: Screening, Treatment, and Follow Up," April, 1994, Bethesda, MD
51. AAMC "Professional Development Seminar for Senior Women in Medicine," March, 1993, Washington, DC
52. Harvard Medical School, "New Pathways in General Medical Education," June, 1991, Boston, MA
53. Mayo Foundation's "Assessment in Medical Education Workshop," October, 1990, Rochester, MN
54. AACR Sponsored Workshop on "Histopathobiology of Neoplasia," June, 1990, Keystone, CO
55. Mayo Foundation, "Interview Skills Workshop," Mayo Medical School, November, 1989 Rochester, MN

#### IV. **Professional Appointments**

##### **American Association for Cancer Research (AACR)**

2006	Co-chair, Grantwriting Workshop (with Dr. William Beck)
2006	Chair, Charlotte Friend Memorial Lecture Selection Committee
2005-2006	Chair, Women in Cancer Research
2005-2006	Chair, Women in Cancer Research, Nominating Committee
2005	Discussion Leader, WICR Professional Leadership Development Workshop
2005	Facilitator, Cancer Research Professional Advancement Workshop
2004-2005	Member, Kirk A. Landon Prize Nominating Committee
2003-2005	Member, AACR Education Committee
2002-2005	Member and Round Table Discussion Leader, Grantwriting Workshop
2002-2003	Member, Charlotte Friend Memorial Lecture Selection Committee
2001	Member, Program Committee, Women in Cancer Research
1999-2000	Member, Nominations Committee, Women in Cancer Research
1998, 1999	Facilitator, Leila Diamond Memorial Breakfast

##### **Society of Gynecological Investigators (SGI)**

2003-2004	Member, Membership Committee
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2004-2005 Member, Nominations Committee

**Gynecologic Oncology Group (GOG)**

2000-present Member, Committee on Experimental Medicine (Developmental Therapeutics Subcommittee; Protocol Review)  
 2000 Member, GOG/NCI-Sponsored Gynecologic Cancers Translational Research Retreat (Planning Committee)

**National Ovarian Cancer Coalition Medical Advisory Board**

2003-2007 Member

**National Ovarian Cancer Early Detection Research Network**

2003-2005 Co-director, (Dr. David Fishman, Director; Northwestern University)

**North Central Cancer Treatment Group (NCCTG)**

1995-1998 Member, Executive Committee  
 1994-1998 Member, Laboratory Correlative Science Committee

**USAMRDC Breast Cancer Research Program**

2000, 2002 Chair, Breast Cancer Review Panel (Pathobiology)  
 1997 Member, Breast Cancer Research External Review Panel (Pathobiology)

**USAMRDC Ovarian Cancer Research Program**

2006-present Chair, Integration Panel  
 2003-present Member, Integration Panel  
 2000, 2001 Chair, External Review Panel (Cell Biology)  
 1999 Member, External Review Panel (Cell Biology)

**USAMRDC Prostate Cancer Research Program**

1998 Member, External Review Panel (Pathobiology)

**NIH, NCI, FDA and VA Appointments**

2008 Member, NCI Cancer Center Site Visit Team (Sylvester Cancer Center, University of Miami, FL)  
 2007-present Member, NCI Board of Scientific Counselors  
 2003 Chair, NIH Bioengineering Research Partnership Review Panel (SBIR)  
 2003 Member, NCI Cancer Center Site Visit Team (Irving Cancer Center, Columbia University, New York, NY)  
 2002 Member, NCI Breast Cancer SPORE Review Panel  
 2001 Member, NIH Center for Scientific Review Study Section Boundary Team for the Oncological Sciences  
 2001 Member, NCI Gynecologic Malignancies PRG Panel  
 2001, 1996 Member, NCI Cancer Center Site Visit Team (Albert Einstein College Medicine)  
 2000 Member (Ad hoc), NIH Experimental Therapeutics-1 Study



	Section
1999-2001	Member, NCI Scholars Program Scientific Review Panel
2000	Member, NCI Mouse Models of Human Cancers Consortium: Ovarian Cancer "Think Tank" (San Francisco, CA)
2000, 1997	Member, NCI Cancer Center Site Visit Team (Moffitt Cancer Center, Tampa, FL)
1999	Member, NCI Ovarian Cancer SPORE Review Panel
1999	Member (Ad hoc), NIH Experimental Therapeutics-1 Study Section
1999	Member, NCI Program Project Site Visit Team (U. California, San Francisco)
1999	Member, NCI Cancer Center Site Visit Team (University of Virginia Medical School), Charlottesville, VA
1998	Member, NCI and Society of Gynecologic Oncologists "Ovarian Cancer Strategic Plan and Implementation" Task Force, Bethesda, MD
1998	Member, NCI Cancer Center Site Visit Team (Kaplan Comprehensive Cancer Center, NY)
1997	Member, NCI Program Project Site Visit Team (M.D. Anderson Cancer Center)
1996	Member, NCI Cancer Center Site Visit Team (University of Iowa)
1996	Member, FDA Site Visit Team (Laboratory of Cell Biology: Division of Cytokine Biology)
1996	Member (Ad hoc), NCI Cancer Center Support Grant Review Committee
1995	Member (Ad hoc), NCI Cancer Center Support Grant Review Committee
1995	Member, NCI Cancer Center Site Visit Team (Norris Cancer Center, Los Angeles, CA)
1995	Member, NCI Program Project Site Visit Team (SUNY, Stony Brook)
1995	Member (Ad hoc), NCI Cancer Center Support Grant Review Committee
1995	Member, NCI Task Force on Intergroup Tumor Banks
1995	Member, NCI Cancer Center Site Visit Team (Vanderbilt Cancer Center)
1994	Member, NIH GCRC Site Visit Team (Univ. Texas Med. Center)
1994	Member, NCI Program Project Site Visit Team (UCLA Medical School)
1993-1997	Member, NIH "Cell Biology & Physiology" Study Section (Subcommittee 2)
1993	Member, NIH GCRC Site Visit Team (Cedars-Sinai Medical Center)

1992	Member, National Science Foundation (EPSCoR Program) Review Panel
1991	Member, U. S. Veteran's Administration "Career Development Program" Review Panel
1991	Member (Ad hoc), NIH "Cell Biology and Physiology" Study Section
1990	Reviewer, U.S. Veteran's Administration Merit Review Board for Oncology

**Symposium Program Committee Memberships**

2003-2004	Ovarian Cancer and High Risk Women Symposium (U. Pittsburgh)
2003-present	Biennial Marsha Rivkin Center Ovarian Cancer Research Symposia (Seattle, WA)
2001-2002	Ovarian Cancer and High Risk Women Symposium (U. Pittsburgh)

**Other Program Review, Site Visit and External Advisory Committee Memberships**

2004-2007	Member, Board of Directors, Van Andel Research Institute and Graduate School (2004-2007; reappointed 2008-2011)
2002-2004	Member, External Advisory Committee, Northwestern Medical Center, Ovarian Cancer Research Program (Supported by NCI CCSG; Dr. Steven Rosen, PI)
2002-2004	Chair, California Breast Cancer Research Program Review Panel
2001-present	Member, External Advisory Board, University of Puerto Rico, Center of Biological Research Excellence (Supported by NIH COBRE award; Dr. Joseph Bonaventura, PI)
2001-present	Chair, Pacific Ovarian Cancer Research Consortium External Advisory Board (supported by NCI SPORE award; Dr. N. Urban, PI)
2001-present	Reviewer (Ad hoc), Ohio Cancer Research Associates
2001	Member, External Advisory Committee, Pathology Graduate Program, U. Maryland School of Medicine, Baltimore, MD
2000, 2001	Member, Pathogenesis Committee, California Breast Cancer Research Program
1999	Member, Hormel Scientific Advisory Committee, Hormel Research Institute, Austin, Minnesota
1991-1992	Member, Peer Review Subcommittee, Minnesota Chapter of American Heart Association
1991	Scientific Consultant/Judge, National American Indian Society for Engineering and Science (NAISES) Science Fair (University of New Mexico)
1990-1997	Reviewer, Fraternal Order of Eagles' Cancer Fund Awards
1990-1999	Reviewer, Mayo Sponsored Clinician Scholar (Rappaport) Awards

1988-1992      Reader/Consultant for AAUW Scholarships/Fellowships, AAUW  
Educational Foundation, Washington, DC




**Editorial Appointments**

2001-2002      Member, *Trends in Cell Biology* Journal Club Board  
1998-2000      Member, Editorial Board, *Drug Discovery*

**Visiting Professorships**

2004              Visting Professor, Pfizer Global Research and Development,  
Groton, CT  
2003              Eppley Vistiting Professor of Oncology, Univ. of Nebraska,  
Omaha, NE  
1995              Visiting Professor, University of Puerto Rico, School of Medicine

## EXHIBIT 2

[Sign In](#) [Register](#)

Search **Nucleotide** for **Go** **Clear**

Display **GenBank** Show **5** Send to **Hide:** ☐ sequence ☐ all but gene, CDS and mRNA features

Range: from **begin** to **end** ☐ Reverse complemented strand Features: ☐ SNP **+** **Refresh**

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**AUTHORS** Reiter,J.L., Threadgill,D.W., Eley,G.D., Strunk,K.E., Danielson,A.J., Schehl Sinclair,C., Pearsall,R.S., Green,P.J., Yee,D., Lampland,A.L., Balasubramanian,S., Crossley,T.D., Magnuson,T.R., James,C.D. and Maihle,N.J.  
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